



Document Title	Issue Date	Document Number	
NEW ACCOUNT APPROVAL	01/29/10	PDQRA-CAD-C005	
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Pharmaceutical Distribution	12/22/08	[PAGE 1* MERGEFORM AT THE PAGE 1*]	DCN-2557

1.0	PURPOSE	The federal Controlled Substances Act requires pharmaceutical wholesalers to maintain effective controls to guard against the diversion of controlled substances. As part of this requirement, Cardinal Health has developed a New Account Approval Process to identify potential customers who may pose a potential risk for the diversion of controlled substances. This policy outlines the required process for the review of potential customers prior to the distribution of any controlled substances.	
2.0	SCOPE	All Pharmaceutical Operations and Customers, Quality and Regulatory Affairs, Supply Chain Integrity.	
3.0	INCLUDED ATTACHMENTS AND FORMS	[HYPERLINK "http://internal.mps.cardinal.net/teams/gradocs/usdistribution/SOPs/HSCSQRA/CAD/PDQRA-CAD-C005-Form1.xls"]	Notification of Corporate QRA Decision on New Account
4.0	POLICY	The Anti-Diversion team, within QRA, Supply Chain Integrity, is responsible for the review and analysis of potential new accounts. The new account approval process encompasses four components: 1) Receipt of questionnaire, 2) Analysis of information, 3) Communication of decision to CCDB team and sales, and 4) Recording of decision	
4.1	Definitions		
	Anti-Diversion e-mail inbox	GMB-QRA-Anti-Diversion or right fax # 614-652-9631.	
	Managed Care e-mail inbox	GMB-QRA-AD-Managed Care	
	CCDB Notification Team	Balistrere, Vita; Budinski, Dennis; Chang, Florence; Grafner, Ben; Kramer, Patty; Lumsden, Scott; Mejia, Sarah; Saul, Amy	
4.2	Procedures for Reporting	The following procedures outline the process for the New Account Approval Process by the QRA team.	
	4.2.1	Receipt of New Account Questionnaire	
		1. Retrieve New Retail Independent Pharmacy Questionnaire from the Anti-Diversion e-mail inbox.	
		OR	
		2. Retrieve New Managed Care Questionnaire from Managed Care e-mail in box.	

DEFENDANT
EXHIBIT

CAH-WV-00030

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- a. Print original e-mail and all related attachments so that author and responsible sales individual are captured.
- b. Place in a yellow folder- this indicates to the QRA team that this is a new account.
- c. Confirm requested attachments are contained within the e-mail or attached otherwise.
- d. If requested materials are incomplete, send an e-mail message to the responsible individuals indicating the review the account will be on HOLD until the required materials are provided to the team.
- e. Managed Care questionnaires require Alternate Site Contract Pricing Declaration and Sit-visit Forms.
- f. If requested materials are complete, then proceed directly to “B” below.

4.2.2 Analysis of Information

- 1. Review every section of the New Retail Independent Account Questionnaire including but not limited to the following sections:
 - a. General information such as address, phone#, and fax # are verified.
 - b. State & Federal Licensure is verified & reviewed for any disciplinary actions related to controlled substances.
 - c. Ownership information
 - d. Prior History and Associations
 - e. Business Information
 - f. Pharmaceutical Needs
 - g. Compliance Agreement
 - h. General Comments section
- 2. Make an educated decision, (or form an educated opinion) based on all the information contained on the form coupled with any external information available, on whether or not the entity poses any potential threat of diversion.

4.2.3 Communication of Decision

- 1. Draft e-mail to CCDB Notification Team and carbon copy (CC) to the responsible sales individuals daily “DEA Limit Over Threshold Report”
 - a. If the decision has be made to **approve** the account then:
 - b. Subject :New Retail Independent Account Approval - “pharmacy name”
 - c. The text of the e-mail shall read “Please find the attached QRA Approval letter for this (state) account. We will continue to use this method of notification to all parties until further notice”.
- 2. Draft the attachment to the e-mail above.
 - a. Open the Excel file titled: “Notification of Corporate QRA Approval on New Account” located on the G: drive within the folder titled “New Retail Independent Accounts”

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- b. Fill in every field available with the accurate information, including checking the box indicating approval of the account.
 - i. The only information which should be input into Customer Segment box are either one of two options:
- c. Retail Independent
- d. Managed Care
 - i. If "Managed Care "is entered then the following field "Sub-Segment" should be populated with either one of two options:
 - Long Term Care
 - Infusion Services
 - ii. Group field shall only be utilized if the entity is affiliated with either Corum / Apria Heath OR Healix.
 - iii. Once this form is complete it must be titled "Approval - (pharmacy name & date), and saved in the G: drive, under the "Approval Letters" sub-folder under the folder "New Retail Independent Accounts".
 - iv. This newly created approval shall be attached to the e-mail described above and sent to the proper recipients.
- 3. If the decision is made to **deny** the account then:
 - a. Follow a similar process described above altering the Subject line to read "Response to Request for New Retail Independent Account".
 - b. The attached excel spreadsheet shall be titled Denial - (pharmacy name, data)
 - c. The text of the e-mail shall describe the reasons for the decision.

4.2.4 Recording of Decision

- 1. Open the Excel file titled "New Retail Accounts-Workbook" located on the G: drive within the folder titled "Running List of New Accounts".
- 2. Input the following information in the appropriate fields of the excel spreadsheet: pharmacy name, address, DEA# , reviewers initials, status of the review process, date of decision notification, sales contact, DC name, and comments.

4.3 Responsibility

On an on-going, continuous basis, the Manager, Regulatory Management, is responsible for the execution of this SOP. In his or her absence, a member of the Supply Chain Integrity team will be assigned the functions.

5.0 APPLICABLE DOCUMENTS

Cardinal Health Alternate Site
Contract Pricing Declaration

Cardinal Health On-Site Visit Form

Compliance Representations and
Warranties for Pharmacy
Customers

[HYPERLINK
"http://www.cardinalhealth.com/RIsurvey"
]
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